K132511

510(K) SUMMARY
[As Required By 21 CFR 807.92(C)]

DEC 2 4 2013

General Information	
Submitter Information	Abbott Diabetes Care, Inc. 1360 South Loop Road Alameda, CA 94502
Contact Person	Vrushali Tembe Sr. Regulatory Affairs Specialist
Telephone	(510) 864 4487
Facsimile	(510) 864-4791
Date	August 9, 2013
Device Information	
Proprietary Name	Freestyle Precision Pro Blood Glucose and β-Ketone Monitoring System
Common Name	(a) System, Test, Blood Glucose, over the Counter (b) Glucose Dehydrogenase, Glucose (c) Nitroprusside, Ketones (Urinary, Non-quant.)
Classification	(a) Glucose Test System (21CFR862.1345), Class II, Product Code NBW (b) Glucose Test System (21CFR862.1345), Class II, Product Code LFR (c) Ketones (Non-quantitative) Test System (21 CFR862.1435), Product Code JIN (d) Calculator/Data Processing Module for Clinical Use (21CFR862.2100), Product Code JQP
Predicate Device	Freestyle Precision Pro Blood Glucose and β-Ketone Monitoring System, cleared under k130094
Legal Manufacturer	Abbott Diabetes Care, Inc. Range Road Witney Oxon OX29 OYL UK

Device Description and Technological Characteristics:

The Freestyle Precision Pro Blood Glucose and β-Ketone Monitoring System is a microprocessor-controlled devices that algorithmically process electrical current from a (biosensor) test strip to compute a diabetic patient's blood glucose reading. The meter is fabricated from standard electronic components housed in an injection molded plastic case that offers easy test strip alignment and insertion, and a custom graphic liquid crystal display (LCD). The LCD will display menu prompts, icons, results, and data. The meter also includes a function key for turning the unit on/off and to select functions.

The meter requires 2 user replaceable standard AA cell batteries. The Freestyle Precision Pro meter is calibrated by scanning the lot specific bar code on the test strip foil label. An assay cannot be performed until the barcode information has been recorded.

The meter automatically stores the last 2,500 test results, which may be a combination of blood glucose or glucose control results. These results can be recalled and displayed again. Additionally, the meters can store up to 6,000 Operator IDs or 1,000 Quality Control tests.

Intended Use:

The Freestyle Precision Pro Blood Glucose and β-Ketone Monitoring System is intended for the quantitative measurement of glucose (sugar) in fresh capillary whole blood from the finger, and from venous, arterial and neonatal whole blood, and for the quantitative measurement of β-ketone (beta-hydroxybutyrate) in fresh capillary whole blood from the finger, and from venous, arterial, and neonatal whole blood when used within 30 minutes after collection. The Freestyle Precision Pro Blood Glucose and β-Ketone Monitoring System is intended for testing outside the body (in vitro diagnostic use) and is intended for multiple-patient use in professional healthcare settings as an aid to monitor the effectiveness of a diabetes control program. This system should only be used with single-use, auto-disabling lancing devices.

The system should not be used for the diagnosis of or screening for diabetes.

The Freestyle Precision Pro Blood Glucose Test Strips are for use with the Freestyle Precision Pro Blood Glucose and β-Ketone Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, and from venous, arterial, and neonatal whole blood. The Freestyle Precision Pro Blood β-Ketone Test Strips are for use with the Freestyle Precision Pro Blood Glucose and β-Ketone Meter to quantitatively measure β-ketone in fresh capillary whole blood samples drawn from the fingertips and from venous, arterial, and neonatal whole blood.

Freestyle Precision Pro Blood Glucose and β-Ketone Monitoring System enables automatic transmission of stored data to a data management system using the docking station (optional), a data upload cable (optional), or wirelessly (optional) in a WiFi enabled facility when the meter and data management systems are properly configured.

Comparison to Predicate Device:

The Freestyle Precision Pro Blood Glucose and β-Ketone Monitoring System has the same intended use and equivalent technological characteristics to the FreeStyle Precision Pro Blood Glucose and β-Ketone Monitoring System (cleared under k130094). The system is identical to the predicate with the exception of the difference noted.

	Predicate Device	**Subject Device**
Devices	Freestyle Precision Pro Blood Glucose and β-Ketone Monitoring System (k130094)	Freestyle Precision Pro Blood Glucose and β-Ketone Monitoring System
Hematocrit	30%-60%	15%-65%

Standard/Guidance Document Referenced:

CLSI EP05-A2, Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline-Second Edition.

ISO 14971:2000, Medical Devices-Application of risk management to medical devices

ISO 15197:2003, In Vitro diagnostic test systems -Requirements for blood-glucose monitoring system for self-testing in managing diabetes mellitus

Performance Characteristics:

The performance of the meter and test strip was studied by healthcare professionals. The studies demonstrate that healthcare professionals can obtain blood glucose results that are substantially equivalent to the current methods for blood glucose measurements, which include the predicate device listed above.

Conclusion:

Results of laboratory testing demonstrate that the performance of the FreeStyle Precision Pro System over the hematocrit range of 15%-65% is acceptable for blood glucose and β-ketone testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 24, 2013

ABBOTT DIABETES CARE INC.
VRUSHALI TEMBE
1360 SOUTH LOOP ROAD
ALAMEDA CA 94502

Re: K132511
Trade/Device Name: FreeStyle Precision Pro Blood Glucose and B-ketone Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, LFR, JIN, JQP
Dated: November 27, 2013
Received: November 29, 2013

Dear Ms. Tembe:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
k132511

Device Name
FreeStyle Precision Pro Blood Glucose and β-ketone Monitoring System

Indications for Use *(Describe)*
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Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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This section applies only to requirements of the Paperwork Reduction Act of 1995.

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